

CLAIMS:

What is claimed is:

- 5 1. A complex of a modafinil compound and a cyclodextrin.
2. A complex of a claim 1, where the modafinil compound has an aqueous solubility of at least 10 mg/ml.
- 10 3. The complex of claim 1, wherein the complex is an inclusion complex.
4. The complex of claim 3, wherein the modafinil compound is modafinil and the cyclodextrin is a β -cyclodextrin.
- 15 5. The complex of claim 3, wherein the cyclodextrin is α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, 2-hydroxymethyl- β -cyclodextrin, 2-hydroxypropyl- β -cyclodextrin, 3-hydroxypropyl- β -cyclodextrin, β -cyclodextrin sulfate, β -cyclodextrin sulfonate, or β -cyclodextrin
- 20 sulfobutyl ether.
6. The complex of claim 5, wherein the cyclodextrin is 2-hydroxypropyl- β -cyclodextrin.
- 25 7. The complex of claim 2, wherein the molar ratio of cyclodextrin to the modafinil compound is from about 10:1 to about 0.8:1.
8. The complex of claim 7, wherein the molar ratio of cyclodextrin to the modafinil compound is about 1:1.
- 30 9. The complex of claim 2, wherein the modafinil compound has an aqueous solubility of at least 20 mg/ml.

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10. The complex of claim 1, wherein the complex is in solution.
11. The complex of claim 1, wherein the complex is a solid.
- 5 12. ✓ A complex of a modafinil compound and a cyclodextrin, wherein the modafinil compound is bioavailable upon oral administration to a subject.
13. ✓ A composition comprising a modafinil compound and a cyclodextrin.
- 10 14. The composition of claim 13, wherein the modafinil compound has an aqueous solubility of at least 10 mg/ml.
- 15 15. The composition of claim 13, wherein the complex is pharmaceutically acceptable.
- 16 16. The composition of claim 15, further comprising one or more pharmaceutically acceptable excipients.
- 20 17. The composition of claim 15, wherein the modafinil compound is modafinil and the cyclodextrin is a β -cyclodextrin.
- 25 18. The pharmaceutical composition of claim 15, wherein modafinil and the cyclodextrin form an inclusion complex.
- 30 19. The composition of claim 18, wherein the inclusion complex is in solution.
20. The composition of claim 18, wherein the inclusion complex is a solid.
21. The composition of claim 14, wherein the modafinil compound has an aqueous solubility of at least 20 mg/ml.

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22. The composition of claim 13, wherein the molar ratio of cyclodextrin to the modafinil compound is from about 10:1 to about 0.8:1.

5 23. The complex of claim 22, wherein the molar ratio of cyclodextrin to the modafinil compound is about 1:1.

24. The composition of claim 13, comprising one or more unit doses of modafinil.

10 25. The composition of claim 24, comprising one unit dose of modafinil.

26. The composition of claim 25, wherein the unit dose is 200 mg of modafinil.

15 27. The composition of claim 25, wherein the unit dose is 100 mg of modafinil.

20 28. A pharmaceutical composition comprising a modafinil compound and a cyclodextrin wherein the composition is aqueous and suitable for oral consumption.

25 29. A method of preparing a complex of a modafinil compound and a cyclodextrin comprising contacting the modafinil compound with the cyclodextrin in an aqueous medium.

30. The method of claim 29, wherein the composition comprises an inclusion complex of a modafinil compound and a cyclodextrin.

30 31. The method of claim 29, wherein the complex is dried and isolated as a solid.

32. A method of treating a disease or disorder in a subject, comprising

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administering a therapeutically effective amount of a composition of a modafinil compound and a cyclodextrin to a subject.

33. The method of claim 32, wherein the composition is administered for
5 the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; and for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain.

10 34. The method of claim 32, wherein the composition is administered orally.

35. The composition of claim 13, wherein the composition provides at
15 least a 25% increase in the blood serum level of a modafinil compound in a mammal relative to a solid dose of modafinil compound.

36. The composition of claim 35, wherein the mammal is a human or a rat.

20 37. The composition of claim 35, wherein the composition is a solution.

38. The composition of claim 13, wherein the composition provides at
least a 50% increase in the blood serum level of a modafinil compound in a mammal within the first hour of administration relative to a solid dose of a modafinil
25 compound.

39. The composition of claim 38, wherein the mammal is a human or a rat.

30 40. The composition of claim 38, wherein the composition is a solution.

41. A composition comprising a modafinil compound and a cyclodextrin wherein the modafinil compound is taste-masked.

42. The composition of claim 41, wherein the modafinil compound is modafinil and the cyclodextrin is a β -cyclodextrin.

5 43. The composition of claim 41, wherein the modafinil compound is present at a concentration of at least 10 mg/ml.

44. The composition of claim 13, wherein the composition is a solid in the form of a tablet or a capsule.

10 45. The composition of claim 13 or 41, wherein the composition is a syrup or elixir.

15 46. The composition of claim 13, wherein the modafinil compound is modafinil and the cyclodextrin is hydroxypropyl- β -cyclodextrin.

47. The composition of claim 46, wherein the composition comprises modafinil in an aqueous 50% hydroxypropyl- β -cyclodextrin solution.

20 48. The composition of claim 13, which has substantially the blood serum profile of FIG. 1.

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